

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

Genesis Health Care, Inc.,

Plaintiff,

v.

Alex M. Azar II, *as Secretary of the United States*
Department of Health and Human Services; George)
Sigounas, *as Administrator of the Health Resources*)
and Services Administration; and Krista Pedley, *as*)
Captain in the United States Public Health Service)
and Director of the Office of Pharmacy Affairs in)
the Health Resources and Services Administration,)

Defendants.

Civil Action No.: 4:19-cv-01531-RBH

ORDER

The Court previously scheduled a hearing on Plaintiff's "Motion for Preliminary Injunction" and "Emergency Motion to Stay" for this Friday, June 28, 2019. *See* ECF No. 36. Having now considered the recent filings in this matter, the Court finds a hearing is unnecessary and will deny the motions.¹

Discussion

In June 2018, Plaintiff filed this action challenging its removal from a federal drug pricing program—the 340B Program—following an audit by the Health Resources and Services Administration ("HRSA").² Within a week, the parties reached an agreement whereby HRSA permitted Plaintiff to be

¹ The Court decides the motions without a hearing pursuant to Local Civil Rule 7.08 (D.S.C.).

² "Section 340B of the Public Health Services Act, 42 U.S.C. § 256b (2006 ed. and Supp. IV), imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities. Those facilities . . . include public hospitals and community health centers, many of them providers of safety-net services to the poor. The § 340B ceiling-price program (340B Program) is superintended by the Health Resources and Services Administration (HRSA), a unit of the Department of Health and Human Services (HHS)." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011). "Immediate responsibility for oversight of the 340B program resides in HRSA's Office of Pharmacy Affairs." *Cty. of Santa Clara v. Astra U.S., Inc.*, 428 F. Supp. 2d 1029, 1031 (N.D. Cal. 2006).

provisionally readmitted to the 340B Program, and the Court stayed this case for nearly a year while the parties attempted to resolve the matter. On May 24, 2019, the parties filed a status report stating they had not reached a resolution, and Plaintiff filed a “Motion for Preliminary Injunction” and an “Emergency Motion to Stay” both seeking preliminary injunctive relief. *See* ECF Nos. 32 & 33.³ Plaintiff “asks the Court to restrain the Defendants from enforcing [the] audit findings” and to “stay[] the imposition of HRSA’s findings.” ECF No. 32 at p. 6; ECF No. 33 at p. 23. However, on June 6, 2019, HRSA voided the audit findings, closed the audit, and determined Plaintiff “has no further obligations or responsibilities in regard to the audit.” ECF No. 41-1.⁴ Based on HRSA’s recent determination, the Court concludes preliminary injunctive relief is not warranted and will therefore deny Plaintiff’s motions seeking such.

To obtain a preliminary injunction, a plaintiff must show (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm without the preliminary injunction, (3) the balance of equities tips in its favor, and (4) the injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see generally* Fed. R. Civ. P. 65 (addressing preliminary injunction motions). A court cannot issue a preliminary injunction if a plaintiff fails to satisfy any of these four requirements. *Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 346–47 (4th Cir. 2009), *vacated and remanded on other grounds*, 559 U.S. 1089 (2010), *reinstated in relevant part*, 607 F.3d 355 (4th Cir. 2010).

The Court finds Plaintiff has not satisfied the second *Winter* factor because it has not made “a clear showing that it is likely to be irreparably harmed absent preliminary relief.” *Real Truth*, 575 F.3d

³ Plaintiff also filed a “Motion to Amend Verified Petition for Judicial Review, Emergency Motion to Stay, and Petition for Declaratory Relief.” ECF No. 31. The Court will grant the motion to amend because it is not opposed and amendment is permitted under Fed. R. Civ. P. 15(a).

⁴ Plaintiff acknowledges “HRSA’s decision to void the audit findings in their entirety and to reverse its decision to terminate [Plaintiff] from the 340B program.” ECF No. 43 at p. 2.

at 347. Although Plaintiff asks the Court to restrain HRSA “from enforcing its audit findings,” ECF No. 32 at p. 6, HRSA has voided the audit findings and closed the audit. Plaintiff itself acknowledges that the audit results were voided “in their entirety.” *See* ECF No. 43 at pp. 1–2. Thus, there is nothing for the Court to preliminarily enjoin. Moreover, the Court cannot issue a preliminary injunction “simply to prevent the possibility of some remote future injury.” *Winter*, 555 U.S. at 22; *see Roe v. Shanahan*, 359 F. Supp. 3d 382, 418 (E.D. Va. 2019) (“A party seeking a preliminary injunction must make a clear showing of ‘actual and imminent’ irreparable harm in the absence of injunctive relief.” (quoting *Direx Israel, Ltd. v. Breakthrough Med. Corp.*, 952 F.2d 802, 812 (4th Cir. 1991))); *see generally Winter*, 555 U.S. at 33 (“Congress plainly intended declaratory relief⁵ to act as an alternative to the strong medicine of the injunction[.]”). The Court will deny Plaintiff’s motions seeking preliminary injunctive relief.⁶

Conclusion

For the foregoing reasons, the Court **DENIES** Plaintiff’s Motion for Preliminary Injunction [ECF No. 32] and Emergency Motion to Stay [ECF No. 33].⁷

IT IS SO ORDERED.

Florence, South Carolina
June 26, 2019

s/ R. Bryan Harwell
R. Bryan Harwell
United States District Judge

⁵ Plaintiff also seeks declaratory relief in this action. *See* ECF No. 33 at pp. 24–25.

⁶ Because Plaintiff has failed to satisfy the second *Winter* factor, the Court need not consider the remaining three factors. *See Henderson for NLRB v. Bluefield Hosp. Co., LLC*, 902 F.3d 432, 439 (4th Cir. 2018) (explaining a district court need not “mechanically consider all four *Winter* factors if one is clearly absent”); *see, e.g., id.* (“[T]he district court correctly applied the *Winter* factors and, upon finding that one had not been satisfied, concluded that the [plaintiff] could not establish the necessary criteria for preliminary injunctive relief.”).

⁷ The Court **GRANTS** Plaintiff’s motion to amend [ECF No. 31] because it is unopposed by Defendants and is permitted under Fed. R. Civ. P. 15(a). Additionally, the Court notes Defendants’ motion to dismiss [ECF No. 41]—which was filed after the Court scheduled the hearing on the other motions—remains pending and this Order does not constitute a decision on the merits of the motion to dismiss.